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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/026,459 02/19/98 XU

H UTXC: 506

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EXAMINER

SHUKLA, R

ART UNIT

PAPER NUMBER

1632

DATE MAILED:

11/16/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No
09/026,459

Applicant(s)

Xu et al

Examiner

Ram Shukla

Group Art Unit

1632



Responsive to communication(s) filed on _____

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11, 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133) Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-43 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) _____ is/are rejected.

Claim(s) _____ is/are objected to.

☒ Claims 1-43 are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☒ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s) _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. Claims 1-43 are pending in the instant application.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-34 and 36-37, drawn to nucleic acids and host cells expressing them, classified in class 536, subclass 23.5.
 - II. Claim 35, drawn to a protein, classified in class 530, subclass 350.
 - III. Claims 38, 40, and 41-43, drawn to a method of protein therapy, classified in class 514, subclass 2.
 - IV. Claims 39-40, drawn to a method of gene therapy, classified in class 514, subclass 44.

3. The inventions are distinct, each from the other because of the following reasons:

The inventions of the groups I and II are patentably distinct each from the other because they are drawn to compositions that have materially different chemical structures and physical properties and utilities. For example, a nucleic acid can be used as probes for identifying or isolating nucleic acids, whereas a protein can be used for producing antibodies. Furthermore, there is nothing on the record to indicate that these compositions are obvious variants. Therefore, the two inventions are deemed patentably distinct.

The inventions of the groups III-IV are drawn to different methods of therapy. For example, the invention of group III is drawn to a method of protein therapy, whereas the invention of group IV is drawn to a method of gene therapy. The methods of the groups III-IV are patentably distinct each from the other because the method of delivery as well as the site of action of the two therapeutics would be different. For example, the method of gene therapy will depend on the vector used for expressing the protein as well as on the route of administration of the vector. The method of protein therapy, on the other hand, will require a different route of therapeutic administration than that of a gene therapy. Additionally, the effects produced by these two methods on gene expression would also be different. Therefore, the methods of groups III-

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IV are patentably distinct each from the other and their analysis will require different search strategy, for example, in the non-patent literature.

The inventions of each of the groups I and II are patentably distinct from the inventions of each of groups III-IV because the methods of groups III-IV can not be used to the make the compositions of the groups I and II. Additionally, the compositions of the groups I and II can be used for practicing methods other than the methods of the groups III-IV. Therefore, the inventions of the groups I-IV are patentably distinct each from the other, and their analysis will require different search strategies, for example, in the non-patent literature.

4. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art shown by their different classification and their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Stanton, can be reached on (703) 308-2801. The fax phone number for this Group is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 305-0196.

Ram R. Shukla, Ph.D.

[Handwritten signature]
R. R. Shukla
Examiner
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